MAY - 6 2009

Visual Features/ Traits

The type of material is shown on the packaging label. PERMANENT aneurysm clips made of Titanium can be identified by spectral color (red or blue), TEMPORARY aneurysm clips made of Titanium are gold colored.
PERMANENT Aneurysm clips made of Phynox are of natural color. TEMPORARY aneurysm clips made of Phynox have gold plated springs and spring shanks.

All Clips and Applying Forceps are delivered non-sterile and they must be cleaned and sterilized before use according Operating Instructions. Clips and Applying forceps are autoclaveable.

The materials used have already been approved in different instruments and implants, containing Titanium and Phynox. The biocompatibility is given by use of these Clips for over 15 years for human applications.
Aneurysm Clips and Applying forceps are produced according to prevailing standards with the technological characteristics of each clip listed on its labelling.

5.8 Intended Use (807.92(a)(5))

Permanent GIMMI Aneurysm Clips (Yasargil) and vessel clips are intended for permanent occlusion of blood vessels and cerebral aneurysms. Likewise, temporary GIMMI Aneurysm Clips (Yasargil) and vessel clips are intended for temporary occlusion of intra cranial blood vessels and cerebral aneurysms. They are also intended to be applied exclusively with the corresponding Clip Appliers.

5.9 Industry Standards / Performance data (807.92 (d))

GIMMI GmbH certifies compliance with relevant ISO/EN/ASTM/AAMIANSI and other device-related standards that apply to the manufacture, packaging, labelling and reprocessing of subject devise including the validation of these processes.

5.10 Non-Clinical Test Results

Based on the equivalence in design and materials to predicate devices and their use since over 15 Years, performance testing was not warranted. The devices will meet the same criteria of Safety and Effectiveness as SE-Devices.

5.11 Bacterial Endotoxins Test

See tests enclosed, Test 063633-10-A and Test 063633-10-B

5.12 Information Bearing on the Safety and Effectiveness (807.92(b)(3))

GIMMI aneurysm clips have the same intended use as predicate devices. They are made of the same material and are produced to the same international and FDA-recognized standards. Slight modifications in design do not adversely affect the safety and effectiveness of these Devices.

In Summary, the

- ✓ Intended Use
- ✓ Performance Attributes
- ✓ Materials and
- ✓ Basic Design

are identical and/or substantially equivalent to SE devices.

The results of design validation raise no new issues of safety and effectiveness.

GIMMI®

5.5 Reason for Submission

Abbreviated 510(k).

5.6 Predicate Devices (807.92(a)(3))

- Aesculap, Inc
- Rebstock – Instrumente GmbH
- V. Mueller Neuro/Spine
- Cardinal Health
- Medicon, E.G.
- Kirwan Surgical Products, Inc

Plus a wide range of other manufacturers/distributors

5.7 Device Description (807.87(a)(4) + (6))

GIMMI Aneurysm Clips and their Clip Applying Forceps are used for the occlusion of aneurysms. "Mini" and "Standard" Clips can only be applied with the according Applying forceps; these forceps are labelled with "Mini" or "Standard".
Clips are available in different sizes and shapes, to have the right size and shape due to the size and shape of the aneurysm.
See item list section 12.

CT- & MR- Safety
GIMMI Aneurysm Clip is manufactured from Titanium acc. to ISO 5832-2 and ISO 5832-3 or Phynox implant steel according to ISO 5832-7.
Non- clinical testing has demonstrated that the GIMMI Aneurysm Clip system is MR compatible. It can be scanned safely under the following conditions:
- Static magnetic field of 1.5 Tesla or less
- Spatial gradient field of 3 Gaus/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 0.03 W/kg for 10 minutes of scanning.

In this non-clinical testing with duration of 10 minutes with EPI (endoplanar imaging) sequences, the GIMMI Aneurysm Clips system produced no temperature rise and no movement.
The test was performed in a SIEMENS MAGNETOM MAESTRO CLASS SYMPHONY MR scanner with a field strength of 1.5 Tesla.
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GIMMI Aneurysm Clips system. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

= MR CONDITIONAL

K081640
3/3

Abbreviated 510(k)

5. SUMMARY of Safety and Effectiveness as required by Section 807.92 (c))

5.1 Submitter

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5.2 Contact Person

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Mr. Kenneth Blake
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One Scanlan Plaza
Saint Paul, Minnesota 55107

Phone: 651-298-0997
Fax 651-298-0018
E-mail BlakeK@SurgicalTechnologies.com

5.3 Date Summary Prepared (8ß7-92(a)(1)) (a))

June 5, 2008

5.4 Devices Names (807.92 (a)(1))

Proprietary Name: Yasargil Clip / Applying Forceps

Common Name: Aneurysm Clip / Clip Applier

Classification Names Clip, Aneurysm / Applier, Aneurysm Clip

Product Code	Regulation #	Class	Classification Name
84 HCH	882.5200	II	Clip, Aneurysm
84 HCI	882.4175	II	Applier, Aneurysm Clip

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2009

Gimmi GmbH
% Scanlan International
Mr. Ken Blake
One Scanlan Plaza
Saint Paul, Minnesota 55107

Re: K081640
Trade/Device Name: GIMMI Aneurysm Clips and Applying Forceps
Regulation Number: 21 CFR 882.5200
Regulation Name: Aneurysm clip
Regulatory Class: II
Product Code: HCH
Dated: March 26, 2009
Received: March 30, 2009

Dear Mr. Blake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson for
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081640

Abbreviated 510(k)

510(k) Number .....

Device Name GIMMI Aneurysm Clips and Applying Forceps

Classification 84 HCI / 84HCH, 882.4175 + 882.5200

Class II

Indications for Use

Permanent GIMMI Aneurysm Clips (Yasargil) and vessel clips are intended for permanent occlusion of blood vessels and cerebral aneurysms. Likewise, temporary GIMMI Aneurysm Clips (Yasargil) and vessel clips are intended for temporary occlusion of intra cranial blood vessels and cerebral aneurysms. They are also intended to be applied exclusively with the corresponding Clip Appliers.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for M&M
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K081640